that claims 1 and 3-9 remain pending. No new matter has been added.

Claims 1 and 15 were rejected under 35 U.S.C. § 112, second paragraph. Applicants have amended the claims to more particularly point out and distinctly claim the subject matter. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1 and 2 were rejected as anticipated by U.S. Patent Number 5,516,781 to Morris et al. (Morris). This rejection is respectfully traversed.

Morris discloses a method for preventing or treating hyperproliferative vascular disease in a mammal by administering an effective amount of anti-proliferative (rapamycin) alone or in combination with mycophenolic acid. The delivery method may include the use of a stent. Specifically, Morris discloses the use of rapamycin in preventing smooth muscle cell hyperplasia, restenosis and vascular occlusion resulting from mechanically mediated injury.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention, as claimed in amended independent claim 1, is directed to a method for treating restenosis. The method comprises an intravascular infusion or delivery by release from a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth and an anti-inflammatory agent for inhibiting smooth muscle cell growth, in therapeutic dosage amounts.

Morris does not address a method for treating restenosis utilizing a combination of agents, including an anti-inflammatory and an anti-proliferative, both of which inhibit smooth muscle cell growth. What Morris does disclose is the combination of rapamycin and mycophenolic acid, both of which are anti-proliferatives. Morris also discloses Cyclosporin A,

which is a known immunosuppressive agent as well as a human carcinogen. Morris also discloses that Cyclosporin A failed to produce any meaningful reduction in intimal thickening (see column 6, lines 64-65). Since Morris fails to address two different types of agents for treating a single condition, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-4 were rejected as anticipated by U.S. Patent Number 6,299,604 to Ragheb et al. (Ragheb). This rejection is respectfully traversed.

Ragheb discloses a coated implantable medical device. In specific embodiments, the medical device comprises a vascular device such as a stent. In one embodiment, one surface of the stent is coated with a bioactive material, and in another embodiment, a second bioactive material is attached to a second surface of the stent. Porous layers may be placed over the bioactive layers to precisely control the release rate of the bioactive agents. As set forth at column 8, lines 30-37, heparin (anti-coagulant) is affixed to the outer surface of the stent. In yet another alternate exemplary embodiment, the stent

is coated with a first coating, then a bioactive agent and then the porous coating to control drug release. In the embodiments wherein the stent comprises holes, the bioactive agent is placed in the holes and then coated with the porous layer.

Ragheb discloses a number of drugs/agents, including heparin, dexamethasone and Taxol®. While Ragheb lists these drugs/agents and potential conditions which may be treated by the drugs/agents, Ragheb fails to disclose or suggest a combination of at least two agents, including an anti-proliferative agent and an anti-inflammatory agent, both of which inhibit smooth muscle cell growth. Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claim 5, was rejected as being unpatentable over Ragheb in view of the article to End et al. (End). Claims 6-7 were rejected as being unpatentable over Ragheb in view of U.S. Patent Number 5,932,580 to Levitzki et al. (Levitzki). Claims 8-11 and 15 were rejected as being unpatentable over Ragheb in view of U.S. Patent Number 6,159,488 to Nagler et al. (Nagler). These rejections are respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Applicants respectfully submit that the references, whether taken alone or in combination, fail to disclose or suggest all of the claim limitations set forth in amended independent claim 1.

Accordingly, reconsideration and withdrawal of the rejections is respectfully requested.

Claims 11 and 15 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 and 25 of copending Application No. 09/850,482.

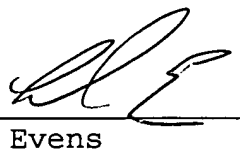
Applicants understand that this rejection is to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendment to the claims of the present invention and any potential amendments made to the claims of the cited application, Applicants shall defer any arguments and/or actions until the applications actually issue.

Applicants would be willing to interview the present case if the Examiner so desires. Accordingly, the Examiner is invited to call the undersigned at (732) 524-2518 if such a call would facilitate the prosecution of this application.

A favorable action on the merits is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached pages are captioned "Version With Markings To Show Changes Made."

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE IN THE CLAIMS

Please amend the claims as follows:

1. (Amended) A [process for the treatment]method for treating restenosis comprising [the]an intravascular infusion or delivery by release from [the]a surface of a stent of a combination of at least two agents, including an anti-proliferative agent for inhibiting smooth muscle cell growth and an anti-inflammatory agent for inhibiting smooth muscle growth, [combinations of at least two drugs to a patient] in therapeutic dosage amounts.

Please cancel claim 2 without prejudice.

3. (Amended) The method of claim [2]1 wherein the anti-inflammatory agent [is]comprises dexamethasone and the anti-proliferative agent is taken from [the]a group of rapamycin, taxol, or vincristine.

4. (Amended) The method of claim 1 wherein the combination of at least two agents [employed]further includes a growth factor or cytokine signal transduction inhibitor [and an anti-proliferative agent].

5. (Amended) The method of claim 4 wherein the cytokine signal transduction inhibitor [is the]comprises a ras inhibitor,

R115777, and the anti-proliferative agent is taken from [the]a group consisting of rapamycin, taxol, or vincristine.

6. (Amended) The method of claim 1 [wherin]wherein the combination of at least two agents [employed]further includes [include] a tyrosine kinase inhibitor [and an anti-proliferative agent].

7. (Amended) The method of claim 6 [wherin]wherein the tyrosine kinase inhibitor [is]comprises tyrphostin and the [antiproliferative]anti-proliferative agent is taken from [the]a group consisting of rapamycin, taxol, vincristine.

8. (Amended) The method of claim 1 wherein the combination of at least two agents [employed]further includes an inhibitor of extracellular matrix synthesis [and an antiproliferative agent].

9. (Amended) The method of claim 8 wherein the inhibitor of extracellular matrix synthesis comprises halofuginone and the anti-proliferative agent is taken from [the]a group consisting of rapamycin, taxol, or vincristine.

Please cancel claims 10-15 without prejudice.